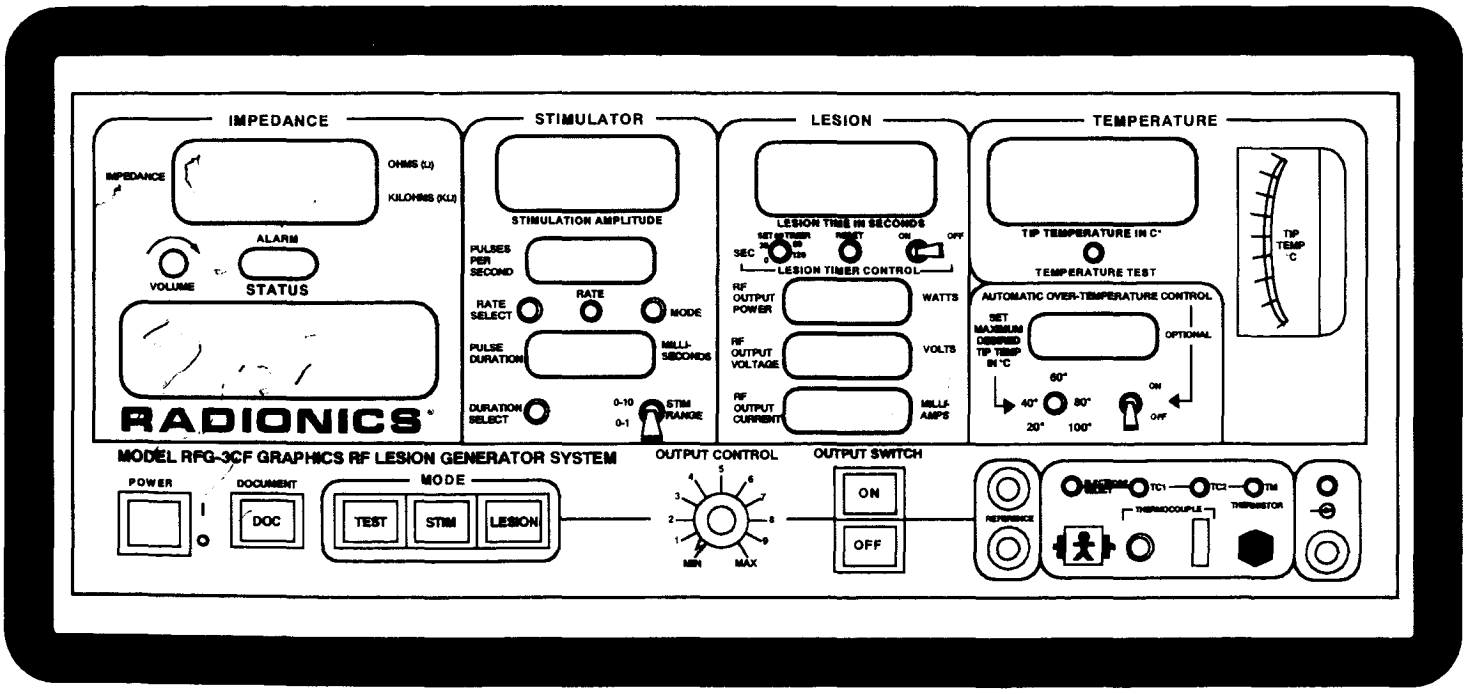
RFG-3CF
LESION GENERATOR
OPERATOR'S MANUAL



914-60-002 Rev. D

RADIONICS, INC.

TITLE AND PUBLICATION NUMBER:
RFG-3CF Lesion Generator Operator's Manual
914-60-002 Rev. D

COPYRIGHT INFORMATION:
© 1997 by RADIONICS, INC., Burlington, MA
All rights reserved.

NOTICES:
This documentation contains confidential and proprietary information. No part of this document may be disclosed, used, reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the expressed written consent of Radionics, Inc. Contact your local Radionics distributor for additional copies.

TRADEMARKS:
RFG-3CF Radio Frequency Lesion Generator is a registered trademark of Radionics. All trade names referenced are the trademarks, registered trademarks, or products of their respective manufacturers.

RADIONICS is a trademark of Radionics, Inc.

CE The RFG-3CF (914) is compliant with the European Communities Council Directive 89/336/EEC concerning electromagnetic compatibility.

LIMITED WARRANTY:
Radionics warrants to the original purchaser that the equipment listed on page 2 shall be free from defects in material and workmanship for a period of one year from the date of shipment. Radionics' obligation under this warranty shall be limited to repair or replacement at the option of Radionics, Inc. The above warranty is contingent upon normal usage and does not cover products that have been modified without Radionics' approval or which have been subjected to unusual physical or electrical stress.

Temperature Monitoring Electrodes: Since electrodes are more subject to abuse the warranty differs. Barring mistreatment and misuse, if the electrode fails in the first three (3) months after date of shipment it is replaced free of charge; if it fails within three (3) to six (6) months it is replaced at 50% of its cost; and if it fails between six(6) to nine (9) months it is replaced at 75% of its cost. Thereafter RADIONICS discontinues its warranty. We note that with proper care TM and TC electrodes have and should function for many years. A common problem is that the insulating coating may have been scraped, in which case it can be recoated at RADIONICS.

CAUTION:
United States law restricts this device to sale by or on the order of a physician.

MANUFACTURED BY:
Radionics, Inc.
22 Terry Ave.
Burlington, MA 01803 USA
(617) 272-1233

AUTHORIZED EUROPEAN REPRESENTATIVE:
Radionics Europe, NV
Gentsesteenweg 40
B-9230 Wetteren BELGIUM
+32-9-366-10-19

Foreword — **Important Information.....i**
General Information
Device Classification
Electrical Safety

Chapter 1 — **Getting Started.....1**
Description
Intended Use
Unpacking the RFG-3CF
Checklist of Components
Turning On and Testing the RFG-3CF

Chapter 2 — **Impedance Section.....5**
Test Mode Off
Test Mode On

Chapter 3 — **Stimulator Mode.....7**
Test Mode Off
Test Mode On

Chapter 4 — **Lesion Mode.....9**
Test Mode Off
Test Mode On

Chapter 5 — **Temperature Monitoring.....13**
Test Mode Off
Temperature
OTC -- Over-Temperature Control
Test Mode On

Chapter 6 — **Output Connections.....17**
Patient Connections
External Connection
Footswitch
Analog Outputs
Serial Output

Appendix A A-1
Sterilization, Care, and Service

Appendix B A-3
Troubleshooting

Appendix C A-5
BNC Chart Recorder Calibration

Appendix D A-9
Specifications
RFG-3CF Block Diagram

Appendix E A-13
Accessories

Foreword:
General Information
Device Classification
Electrical Safety

General Information

Safe and effective lesioning is dependent not only on equipment design, but also on factors under the control of the operator. Do not attempt to operate the RFG-3CF prior to completely reading and understanding the directions for use.

Warning: **Electric Shock Hazard**
There are no user serviceable parts inside the RFG-3CF. To avoid electric shock, return the device to Radionics for servicing. Refer to the service manual for maintenance and calibration instructions.

Warning: **Hazardous Electrical Output**
This equipment is intended for use by qualified personnel only.

Do not use within 15 feet (4 meters) of a cardiac pacemaker.

This equipment has an output which is capable of causing a physiological effect.

Risk of Burns and Fire: Do not use near conductive materials such as metal bed parts or inner spring mattresses.

Warning: **Protective Earth Grounding**
Grounding reliability can only be achieved when the equipment is plugged into a receptacle marked "Hospital Grade". Any interruption of the Protective Earth conductor will result in a potential shock hazard which could cause injury to patient or operator.

Device Classification

Classifications as per IEC 601-1/1988, the manufacturer describes the RFG-3CF as:

Type of protection against Electric Shock:	Class I
Degree of protection against Electric Shock;	Type BF Defibrillator Protected
Degree of harmful ingress of water:	Ordinary
Mode of Operation:	Continuous Use
Degree of Safety in the Presence of Flammable Anesthetic Mixture with Air, Oxygen or Nitrous Oxide:	Not suitable for use

Electrical Safety and EMC

The Radionics RFG-3CF has been tested to and meets the requirements of the following Electrical Safety Standards:

IEC 601-1 Medical Electrical Equipment (1988)

IEC 601-2-2 Particular Requirements for the Safety of High Frequency Surgical Equipment (1992)

The Radionics RFG-3CF has been tested to and meets the requirements of the following EMC Standards:

IEC 601-1-2 Collateral Standards: Electromagnetic Compatibility (1993)

The following standards apply:

CISPR 11 Group 1, Class A, ISM

IEC 1000-4-2, 1000-4-3, 1000-4-4, 1000-4-5

Electrical Safety Information

The RFG-3CF is a radio frequency lesion generator designed to produce local tissue heating at the tip of an electrode by the presence of radio frequency current. Special isolation transformers are imposed between power lines and internal RFG-3CF circuitry, resulting in very low leakage current.

Warning: A needle electrode should not be used as the dispersive electrode, as it is possible to burn the patient at this site due to high current densities. In all applications, care should be taken to maximize the surface area of the dispersive electrode. The dispersive electrode should be reliably attached with its entire area to the patient's body and as close to the operating field as possible.

The risk of igniting flammable gases or other materials is inherent in lesioning and cannot be eliminated by device design. Precautions must be taken to restrict flammable materials and substances from the electrosurgical site. The use of flammable anesthetics and nitrous oxide and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are suctioned away. Flammable agents used for cleaning or disinfecting or as solvents of adhesives should be allowed to evaporate before the application of RF surgery. There is a risk of pooling of flammable solutions under the patient and in body cavities. Any fluid pooled in these areas should be removed before the equipment is used.

Warning: Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned after the initial application of the dispersive electrode.

Warning: Set the output power setting as low as possible for the intended purpose.

Warning: Electromagnetic interference (EMI) produced by the RFG-3CF during normal operation may adversely affect the performance of other equipment. The performance of this device may be adversley affected by other high frequency surgical devices in close proximity. If problems occur, separate the devices.

Warning: The use and proper placement of dispersive electrodes is a key element in the safe and effective use of this lesion generator, particularly in the prevention of burns. Read and follow the dispersive electrode manufacturer's instructions for preparation, placement, surveillance, removal and use of any dispersive electrode. The use of dispersive electrodes which meet or exceed ANSI/AAMI requirements (HF18) is recommended.

Warning: Use a large area for the dispersive electrode, preferably a large area gel-pad or similar "ground" plate to disperse and return RF current over as large an area as possible, and thus minimize heating effects at that electrode. Use broad ground plates or gel pads as dispersive electrodes to avoid high current densities and resultant burns in adjacent tissue.

The ground pad should be placed in close proximity to the lesion site (e.g., for head and neck procedures at the scapula and for lumbar and thoracic procedures at the legs. Never place at the gluteus maximus).

Warning: Observe the dispersive electrodes during lesioning for signs of excess heating.

Warning: The long-term risks of protracted fluoroscopy and creation of RF lesions have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children. Furthermore, the risk/benefit in asymptomatic patients has not been studied.

Warning: The RFG-3CF is capable of delivering a significant amount of output. Patient or operator injury can result from improper handling of the active electrode and dispersive electrode, particularly when operating the generator. During energy delivery, the patient should not be allowed to come in contact with metal parts which are earthed or which have an appreciable capacitance to earth. The use of antistatic sheeting is recommended for this purpose. Unshielded leads (active or return) should be positioned so that they cannot come into contact with the patient or other leads connected to the patient and so that they do not run parallel to nearby leads.

Warning: Skin-to-skin contact should be avoided to prevent the possibility of accidental burns. It is recommended to place gauze pads in probable skin-to-skin contact sites (e.g., armpits, etc.).

Warning: Electrodes and probes of monitoring, stimulating, and imaging devices can provide paths for high frequency currents even if they are battery powered, insulated, or isolated at 60Hz. The risk of burns can be reduced, but not eliminated, by placing the electrodes or probes as far away as possible from the lesion site and from the dispersive electrode. Protective impedances incorporated into the monitoring leads may further reduce the risk of these burns and permit continuous monitoring during energy delivery. Needles should not be used as monitoring electrodes during such procedures.

Warning: Potentially hazardous conditions may exist when accessories of similar connector types are combined. Use only appropriate accessories certified by an accredited test body.

Warning: Always inspect insulated electrodes and cables for damage before each use. If an electrode or cable has cracked or scraped insulation, RF current will flow out these cracks and not be concentrated at the tip. This can cause an abnormal temperature rise and abnormally high current and low voltage readings on the meters (similar to a short circuit).

Warning: Never proceed in a temperature monitored procedure if the generator does not read body temperature before you begin delivering RF energy.

Warning: Raise the temperature slowly, particularly with large electrodes. Displayed temperature lags behind the actual temperature due to the thermal mass of the electrode.

Warning: The stimulator should not be used in any situation where the stimulating electrode could potentially come in contact with heart muscle, since these low frequency pulses could cause a serious physiological effect.

Warning: Verify functional safety of the device before each use.

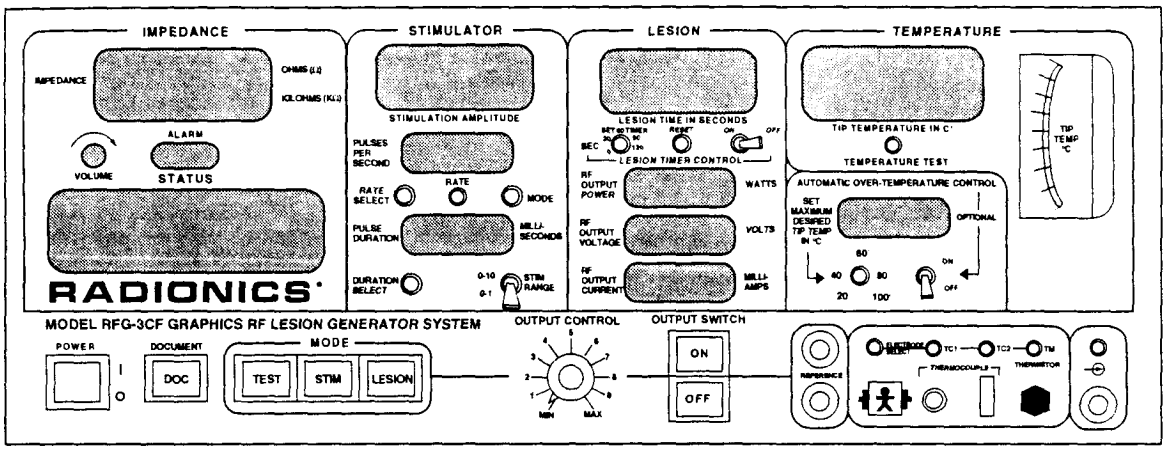
Caution: Increase temperature at a slow and steady rate to prevent temperature overshoots.

Caution: Concentrate on maintaining the desired temperature response. If you cannot get a temperature rise, the voltage and current meters will indicate if the problem is an open circuit (abnormally low current and high voltage) or short circuit (abnormally high current and low voltage).

Notice: Always have spare electrodes and cables on hand in case a problem arises with the first one during a procedure.

Notice: Reusable cables and accessories should be periodically function and safety tested. Position cables to avoid contact with the patient or other leads.

Chapter 1
Getting Started



Description

The RFG-3CF is a microprocessor-based lesion generator capable of supplying up to 50 watts of radio frequency power while continuously monitoring both the tissue impedance and the temperature at the tip of the selected electrode. It contains a stimulator section to facilitate the proper placement of the electrode before lesioning. Additionally, there are several built-in features, such as an over-temperature control and audio tones that indicate impedance and temperature values. Finally, the status display indicates the mode and gives other important information, such as open circuit, temperature over boiling, etc. All of these functions are described in more detail in subsequent chapters.

Intended Use

The RFG-3CF is intended to create lesions in nervous tissue. It is indicated for use in neurosurgery, orthopedics, and podiatry.

Unpacking the RFG-3CF

Box 1 contains:

RFG-3CF
Operator's Manual and test records.

The RFG-3CF is packed surrounded by foam in a double-walled box. Remove the top foam and lift out the unit by the

handle. Place the Operator's Manual and test records in a safe place for later reference.

Notice:	Save packaging materials for use in the event that the RFG-3CF is shipped back to Radionics.

Cables and additional accessories are packed in Box 2.

Box 2 contains:

RFG-3C-TB Tool Box
C119, C118-F, or C120 Power Cord, depending on destination
C104-TM Connecting Cable for TM Electrodes
C121 5' Black Reference Cord
(2) SK-1R Red-Anodized Sterilizable Knobs
(2) Spare Fuses CON-FU-0042 (1.6A or -0045 (3A)
RFG-GP-S Grounding Pad w/Shrouded Plug (International Sales only)
RFG-3C-FS-1 Footswitch (Waterproof)
CA-TC TC Active Jack Adaptor.

Turning on and Testing the RFG-3CF

After unpacking the RFG-3CF from the shipping box, plug the power cord into the rear of the unit.

Caution:	Make sure that the wall outlet voltage and frequency match those on the serial number label on the rear of the unit.

Plug the power cord into the proper AC receptacle. Rotate the RFG-3CF's carrying handle downward by pressing the buttons on both sides of the handle. The handle will lock into a number of different positions to allow it to be used as an adjustable tilt stand as well as a carrying handle. Adjust this handle for easy viewing of the front panel.

Notice:	No electrodes or cables should be connected to the RFG-3CF.

Connect the footswitch to the rear panel for this test. Press the green POWER switch. The RFG-3CF performs the following self-tests: RAM test, ROM test, and a display test. During the display test verify that all LED's are lit. If any LED is not functioning, do not use the device and call Radionics. The Status window should read OUTPUT OPEN CIRCUIT, SELECT MODE. The Temperature and Impedance LED displays should read "---". The green light above TC1 should light.

Press the TEST button. The button should illuminate and the status window should display TEST MODE ON, SELECT MODE. The impedance meter should read 100Ω ±20%. Both the analog and digital temperature meters display the temperature of the test resistor inside the RFG-3CF, approximately room temperature.

Notice:	If the temperature is less than 20°C the display reads "---".

Press the STIM button. It should illuminate. Set the Output Control knob to zero. The Stimulator section windows should display approximately 0 volts, 50 Hz rate, 1.00 ms duration, and the "V" LED will be illuminated, indicating voltage stimulation mode is selected. The status window should display TEST MODE ON, STIM MODE READY. If the knob is not set at zero, the display reads TEST MODE ON, SET CONTROL TO ZERO. Depending on the position of the Output Control knob and the Stimulator range toggle switch, the stimulator voltage reads approximately 0-1 volt in the low range and approximately 0-10 volts in the high range.

Turn the Output Control knob to Min, and depress and hold the footswitch. The ON button should light, the Rate LED should begin to flash, and the status window should display TEST MODE ON, STIM OUTPUT ON. Release the footswitch to change settings.

Press the RATE button to change the rate setting. Press the RATE button repeatedly; the speed of the LED flashes changes correspondingly. Press the DURATION button repeatedly to change the duration setting. Select One Shot mode by toggling the RATE SELECT button until dashes are displayed in the Frequency window. The Rate LED should stop flashing, the status display should read TEST MODE ON, and unit should switch to output off. The Rate LED flashes once each time the footswitch is pressed.

Press the MODE button to deselect One Shot mode and select Current Stimulation mode. The mA LED will illuminate in the Stimulation window, indicating Current Stimulation mode is selected. Use the RATE button to select 5 Hz. The Output Control does not have to be set to Min. Depress and hold the footswitch. The ON button should be illuminated, the Rate LED begin to flash, and the Status window display TEST MODE ON. Release the footswitch to change settings.

Press the LESION button. The button should illuminate, and the LESION TIME window should display the set time. VOLTAGE, CURRENT and WATTS should read zero. The status window should display TEST MODE ON, LESION MODE READY. If the output control knob is not already set at Min, the window will display TEST MODE ON, SET CONTROL TO ZERO. The OFF button should be lit. If the OTC toggle switch is in the ON position, the Automatic Over-Temperature Control window indicates the over-temperature set point. If the toggle is OFF, the window is blank.

Place the Lesion Timer Control switch in the OFF position to perform this test. Turn the SET TIMER knob to zero. The timer window displays 00 or 01 sec. With the knob at its maximum setting, the TIMER display should read between 115 and 120 sec.

Move the OTC toggle switch to the ON position and turn the temperature knob to 20 degrees. The OTC window should display between 15 and 25 degrees. Turn the knob to its maximum setting. The display window should read between 95°-100°C. Move the OTC toggle switch to the OFF position.

Turn the Output Control knob to Min. Press and hold the footswitch. Turn up the Output Control knob until the RF VOLTS display reads 50 volts. The RF current display should read approximately 500 mA and the RF watts display should read 25 watts. If the RF power is left on long enough, the test resistor will begin to heat up. This can be seen by an increase in the Temperature meter reading. Release the footswitch.

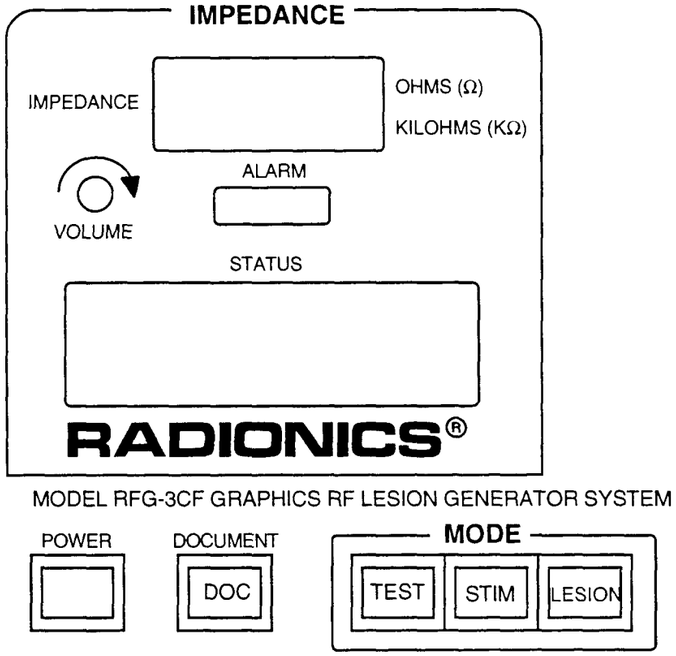
Push the Electrode Select button. The TC2 electrode is selected, and the green light moves to above the TC2 jack. Press the button again. The TM electrode is selected, and the green light above the TM jack illuminates. If pressed a third time, the TC1 electrode is selected and the green light above the TC1 jack again illuminates.

Push the TEMPERATURE TEST button. The temperature display and the analog meter should read approximately 40 degrees and then change to 90 degrees after a few seconds. Repeat for the TC2 and TM electrodes.

The preliminary test of the RFG-3CF is complete.

Contact your local Radionics distributor if you have any questions.

Chapter 2
Impedance Section



Test Mode Off

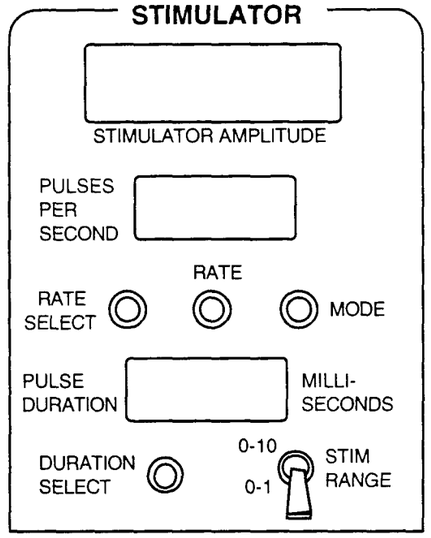
The RFG-3CF continuously measures the impedance between the selected electrode and the dispersive electrode. The appropriate ohms (Ω) or kilo-ohms (kΩ) LED will light. If the measured impedance exceeds 5,000 ohms, the Impedance window will display dashes (---), and the status window will display OUTPUT OPEN CIRCUIT. There is also an audible tone that is proportional to impedance when not in lesion mode (the tone is proportional to the temperature when in Lesion mode). The volume can be adjusted by turning the Volume knob.

Notice:	Confirm the TEST button is not illuminated when attempting to deliver energy to an electrode. Otherwise the energy is delivered to the internal test load, and no energy is delivered to the tissue.

Test Mode On

The test resistance is 100 ohms ±20%. Whenever the test button is pushed, the status window displays TEST MODE ON, and the Impedance window should display approximately 100 ohms.

Chapter 3
Stimulator Mode



Test Mode Off

The stimulator is selected by depressing the yellow STIM mode button.

Voltage or Current stimulation mode is selected by depressing the MODE button. The "V" or "mA" LED will illuminate, indicating which mode is selected.

The pulse amplitude is displayed in the Stimulator Amplitude window. It is increased by turning the Output Control knob clockwise.

The pulse frequency is indicated in the Pulses Per Second window and is changed by pushing the Rate Select button. When the stimulator is activated, the RATE light flashes at the selected rate as an indicator that the stimulator is working.

The pulse duration is indicated in the Pulse Duration window and is changed by pushing the Duration Select

button. Selecting the One Shot mode sends a single pulse to the output each time the stimulator is activated. One Shot mode is selected by depressing the RATE SELECT button until dashes are displayed in the Pulses Per Second window.

The stimulator is activated by depressing and holding down the footswitch while in STIM mode. The microprocessor prevents the stimulator from being turned on when in Voltage Stimulation mode without first setting the Output Control knob to Min.

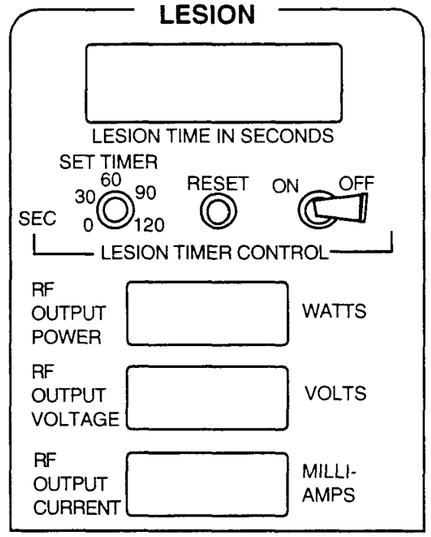
The stimulator can be turned on independent of the Output Control Knob position when Current Stimulation mode is selected.

Notice:	Note that the readings of the stimulator voltage or current, pulse frequency and pulse duration indicate their respective settings only. A value shown for pulse amplitude does not mean an output is being produced. ***The status window displays STIM OUTPUT ON and the rate light flashes when a stimulus is sent to the output.***
Notice:	In Current Stimulation mode dashes are displayed, indicating the impedance is too high to maintain a constant current. This is corrected by lowering the stimulation current.

Test Mode On

The functions are identical as described above, except the output is directed to a 100 ohm internal test resistor instead of the selected electrode jack.

Chapter 4
Lesion Mode



Test Mode Off

Select Lesion mode by pressing the LESION mode button until it illuminates.

The lesion timer indicates lesion time in seconds and, if activated, counts up from zero to the set time, then disables the RF output. The timer can be set between 0 and 120 seconds by turning the SET TIMER knob in the Lesion Timer Control section. Pushing timer RESET resets the timer to zero.

If the lesioning is aborted prior to the timer disabling the RF output, the elapsed time freezes on the timer window until the RESET button is pressed or the output is reactivated.

The lesion timer is enabled by moving the ON-OFF toggle switch to the ON position, and is disabled by moving it to the OFF position.

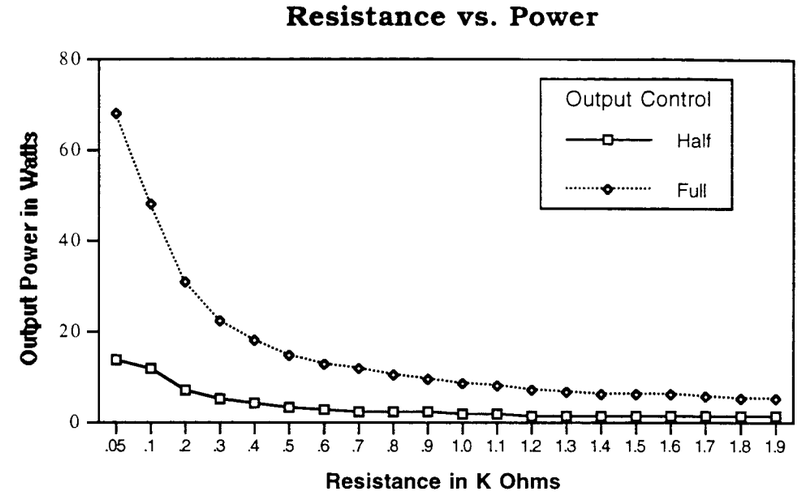
The timer actually starts timing (if enabled) when the

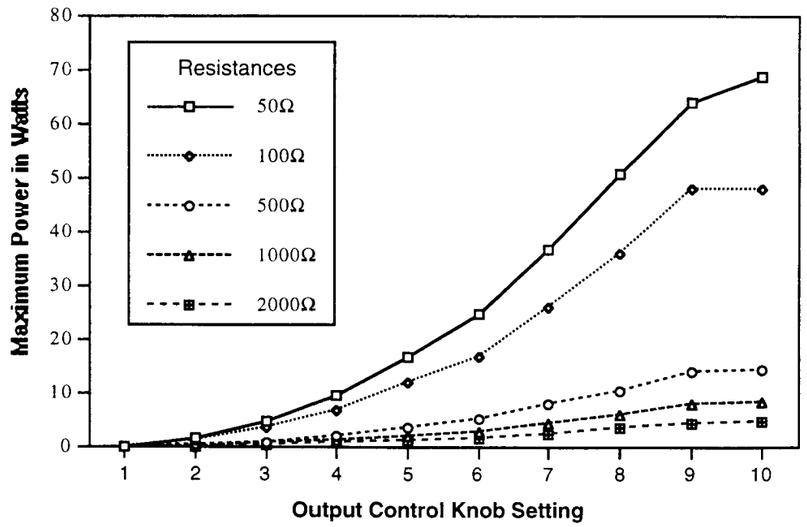
footswitch is pushed. It may also be enabled or reset at any time after the lesion power is turned on.

Turn on RF power by pushing the footswitch. The power is increased or decreased by turning the Output Control knob. The micro-processor prevents turning the RF on when the Output Control knob is set above Min. The RF output current, volts and power are displayed in their respective windows.

Test Mode On

The functions are identical to those described above, except the output is directed to a 100 ohm internal test resistor instead of the output jacks.

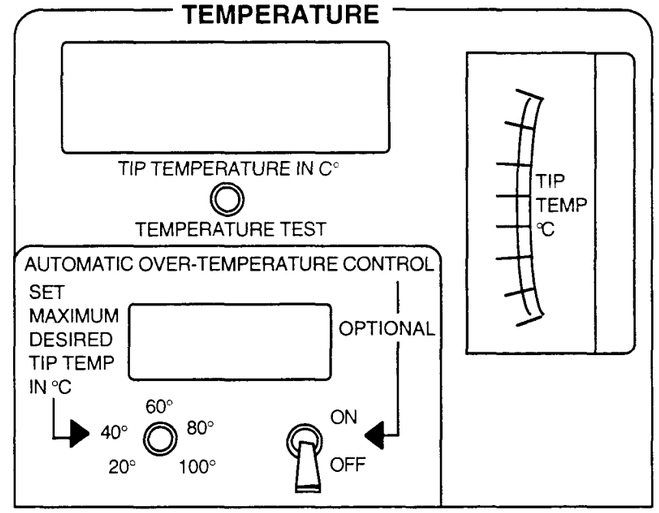




IMPORTANT NOTE: Output power varies with mains voltage ±20%. These readings were taken on a 240V/50Hz unit at 240Vac~. The output power displayed in the above graphs is the measured, not the displayed, value. The displayed value may vary by ±10%.

[This page intentionally left blank.]

Chapter 5
Temperature Monitoring



Test Mode Off

Temperature

Temperature is displayed in the tip temperature window and indicates the tip temperature (°C) of the selected electrode. Pressing the Temperature Test button performs a 40° and 90° test of the circuitry chosen by the Electrode Select button. The measured output is displayed in the temperature window and on the analog meter so that a functional test and a calibration check can be performed at any time. It is considered acceptable if the temperature displayed is within ±2 °C of actual value, i.e., 38-42° for 40° test and 88-92° for 90° test.

OTC -- Over-Temperature Control

The OTC prevents the selected electrode tip temperature from exceeding the preset temperature displayed in the over-temperature control window. If this temperature is exceeded,

the amplitude of the RF power is reduced slightly. This is done by a feedback mechanism that regulates the temperature at the preset value. However, this is only true if the set power is between the set temperature and 5° higher than set temperature. If the latter occurs, the status displays POWER SET TOO HIGH, and the alarm sounds. The Over-Temperature Control can be set between 20°-100° with the Set Temperature knob. Note that the OTC circuit is activated only if the OTC toggle switch is in the ON position. If it is in the OFF position, the set temperature window is blank, and the operator must manually adjust the Output Control knob in order to maintain a desired temperature.

The OTC can be used in two different ways.

1. The OTC can be used to protect against the tip temperature rising significantly higher than the desired lesioning temperature. For example, with the set temperature at 90°C, the over-temperature control prevents boiling from occurring. Similarly, if the lesioning temperature was to be 80°C, set the over-temperature control at 85°C. The RF power would then be turned up and controlled by the surgeon, but would automatically engage if the temperature rose above 85°C.

2. The OTC can also be used as an automatic temperature control. Set the over-temperature control at the desired lesion temperature and slowly turn up the RF power until the set temperature is reached. The microprocessor now regulates the RF power to maintain this temperature.

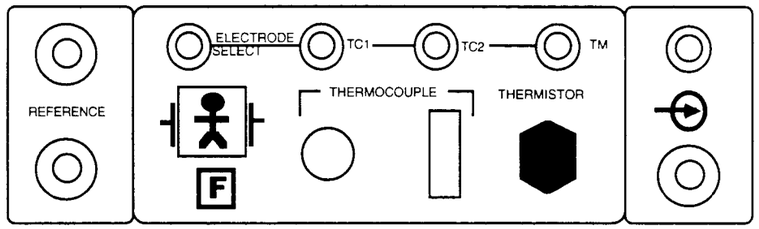
Notice:	When using this mode, the temperature can vary ±2°C from the set temperature. The microprocessor is setting the correct amplitude and is reacting to the thermal time constants of the tissue. If the RF power is too low, the OTC does not activate, and the lesion generator functions as all previous models. If the RF power is turned up so that boiling occurs, the RF is turned off and a warning appears in the status window.

Test Mode On

When the TEST button is illuminated, the temperature displayed is the temperature of the internal thermocouples or thermistor (depending on which electrode type is selected). This allows testing of the RF generator, temperature circuitry, and OTC if desired. All other functions are as described in *Test Mode Off*.

[This page intentionally left blank.]

Chapter 6
Output Connections



Patient Connections

Type BF defibrillator protected.
Neutral Electrode isolated at low and high frequencies.

Patient connections are made via two output jacks marked "Reference". Either one may be used to accept the dispersive electrode plug. Electrode jacks are selected by repeatedly pushing the electrode select button until the desired LED lights.

External Connection

Three things happen when the External Connection button is pushed:

1. The button illuminates.
2. The status window displays External Connection.
3. The external connection jack is connected to the selected electrode.

Use the External Connection button to connect an external device to the tip of the electrode without removing the electrode or the cable from the patient or the device.

Warning:	Any device connected to the External Connection jack must be of at least type BF Protection Against Electric Shock and meet the requirements set forth in IEC 601-1-1.

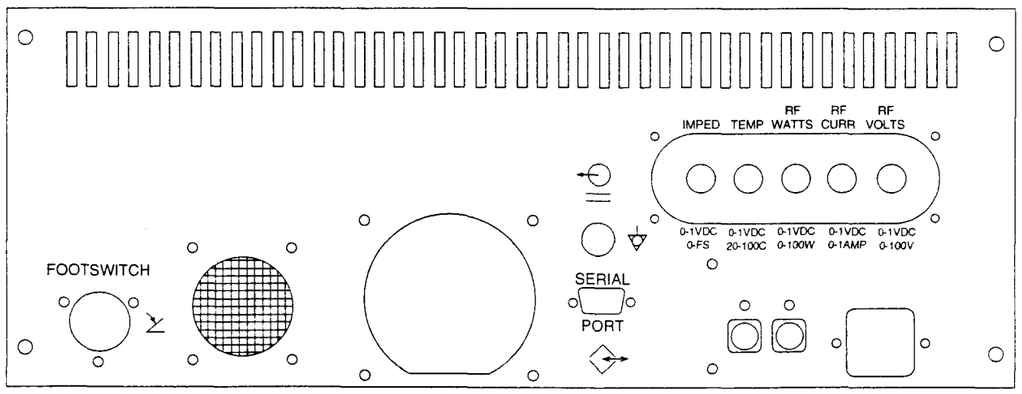
Footswitch

The RFG-3CF is supplied with a footswitch of the momentary type. The footswitch must be plugged into the jack marked FOOTSWITCH on the rear of the unit. The RF output may only be activated by depressing and holding the footswitch. RF output is deactivated when the footswitch is released.

Analog Outputs (DC Volts)

Analog output BNC connectors are supplied on the rear of the RFG-3CF for Impedance, Temperature, RF Watts, RF Current, and RF Volts. The outputs are adjusted to 1volt DC for full scale reading; this is a standard input for most chart recorders.

Notice:	Always record the wattage readings that correspond to a given temperature for a given technique. This gives extra guidance and helps Radionics diagnose problems. It is recommended that analog recordings are made for as many parameters as possible to provide data when questions arise. At minimum, Impedance, Temperature (if being used), and Watts should be recorded.



Serial Port

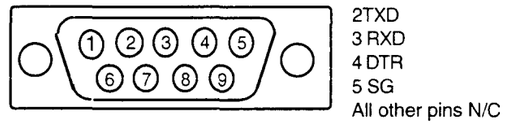
A serial output is provided on the back of the unit. This output conforms to the RS232C serial output configurations. If a LaserJet printer is serially connected to the 9 pin output connector on the back of the unit, a graph of the front panel settings versus time is printed by pressing the DOC button.

Notice:	The printer must use the HP* PCL command set.

The following printers have been tested with this unit.

1. HP LaserJet
2. HP LaserJet IIP
3. HP LaserJet IIP Plus (with optional serial interface)
4. Okidata 830 in HP emulation (with optional serial interface)

The connector is configured as shown below.



*HP is a registered trade mark of Hewlett Packard

[This page intentionally left blank.]

Appendix A
Sterilization, Care, Service

Sterilization

Caution: It is recommended that all cables and electrodes be gas sterilized (ETO). The cables may be standard (gravity) autoclaved (121°C).

The sterilizable knob may be flash autoclaved (132°C).

No other parts may be autoclaved.

Care

The RFG-3CF may be cleaned by wiping with a soft cloth dampened with a mild detergent. Do not allow liquid to get into the generator.

The cables, electrodes, and cases may be wiped with mild cleaning solutions, taking care to keep moisture out of the connectors. Store in a clean, dry, and non-corrosive atmosphere. The lesion generator is designed to withstand all normally encountered environmental conditions. Do not drop or bang the lesion generator.

Service

Caution: The RFG-3CF is not user serviceable, and the generator should be returned to Radionics if any problems arise.

To ensure accuracy of unit output and displays, return the unit to Radionics for yearly calibration.

In case of failure or malfunction of the device, discontinue use and report the failure or malfunction to Radionics.

For any electrical malfunction, accident, misuse, alteration or other damage, return unit immediately to Radionics with a problem description.

Contact Radionics Customer Service for further assistance if needed.

Fuse Replacement

Warning: Risk of fire. Fuses must be replaced as marked.

The RFG-3CF has two fuses, one for line and one for neutral conductors. Replace with:

3.0A 250V for 100V-120V line operation.
T1.6A L 250V for 220-240V line operation.

("T" indicates slow blow or time lag fuse.)

Appendix B
Troubleshooting

Troubleshooting

PROBLEM	*POSSIBLE CAUSE*
Unit will not turn on	Bad AC outlet
	Defective power cord
	Blown fuses
No output	Unit in TEST MODE
	No ground connection
	Problem with electrode
	Break in electrode cable
	Wrong electrode selected
No impedance readings	No ground connection
	Open circuit in cabling
RF output will not turn on	Time set to zero
	Output control set to a value other than zero
	Footswitch defective
Power shuts down prematurely	Set time on the timer is too low
No response when a button is pressed	Button is stuck in the depressed position.
No temperature reading	Not using temperature monitoring electrode.
	Bad cabling or electrode (can be verified if RFG-3CF passes TEMPERATURE TEST)
Stimulator voltage too low	Range switch in low position
Stimulator will not turn on	Output control off zero
Lesion output power low and alarm sounds	OTC set too low

Warning: A COMMON PROBLEM THAT OCCURS DURING TRIGEMINAL NEURALGIA (TIC) PROCEDURES IS THE PATIENT MAY EXPERIENCE A STIMULUS EVEN WHEN THE GENERATOR IS UNPLUGGED FROM THE POWER SOURCE.

This occurs because the patient acts as an electrolyte, and when two plates of dissimilar metals (electrode and ground pad) are attached, a battery is formed. If a discharge path is connected across this voltage, the charge carriers present will flow through it, discharging the potential. This is the case when a lesion generator is connected across a patient via an electrode and ground plate. This discharge action may stimulate the patient if near the trigeminal nerve.

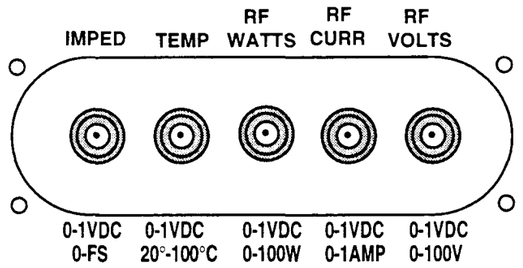
Use an electrode and ground plate composed of the same metals to remedy this. No significant charge develops across them when connected to the patient, and no current flows when connected to the generator.

Radionics, Inc. will supply (international only) , by request, a stainless steel ground pad [RFG-GP] for use with Radionics electrodes.

If unable to resolve the problem, contact Radionics Technical Support.

Appendix C
BNC Chart Recorder Calibration

BNC Chart Recorder Calibration



The following equipment is needed for this calibration:

one 5kΩ 1/4 watt 5% resistor
one C102-B black reference cord
one lesioning electrode and cable

Procedure

IMPEDANCE

1. Connect the chart recorder to the IMPED BNC connector on the back of the RFG-3CF.
2. Connect the electrode and reference cords to their respective front panel jacks.
3. Connect the ends of the cords together.

Caution: **DO NOT TURN THE RF ON WHILE THE CORDS ARE SHORTED.**

4. Turn the RFG-3CF and the chart recorder on.
5. Adjust the chart recorder zero control until the pen reads zero.
6. Connect the electrode and reference leads from the unit to the 5kΩ resistor.
7. Adjust the chart recorder gain control for full scale reading.

8. Remove both of the cords.

TEMPERATURE

1. Connect the chart recorder to the TEMP BNC connector on the back of the RFG-3CF.
2. Press the Temperature Test button on the front panel.
3. When the temperature display reads 40°C, adjust the chart recorder zero for the position that you want the 40° line.
4. When the temperature display reads 90°C, adjust the chart recorder gain for the position that you want the 90° line.

WATTS

1. Connect the chart recorder to the WATTS BNC connector on the back of the RFG-3CF.
2. Adjust the chart recorder zero control until the pen reads zero.
3. Press the TEST button on the front panel of the unit to put the unit into test mode.
4. Press the LESION button to put the unit into lesion mode.
5. Switch the timer ON/OFF switch to the OFF position.
6. Turn the Output Control knob to zero and press the ON button.
7. Turn the Output Control knob up slowly until the WATTS display reads 40.
8. Adjust the chart recorder gain control until the pen is where you desire 40 watts (near full scale).
9. Turn the Output Control knob to zero.

CURRENT

1. Connect the chart recorder to the CURRENT BNC connector on the back of the RFG-3CF.
2. Turn the chart recorder zero adjust until the pen reads zero.
3. Turn the Output Control knob up until the Current display reads 500mA.
4. Adjust the chart recorder gain control until the pen reads half scale.

VOLTS

1. Connect the chart recorder to the VOLTS BNC connector on the back of the RFG-3CF.
2. Adjust the chart recorder zero control until the pen reads zero.
3. Adjust the Output Control knob until the volts display reads 50V.
4. Adjust the chart recorder gain control until the pen reads half scale.

[This page intentionally left blank.]

Appendix D
Specifications
RFG-3CF Block Diagram

Specifications for the RFG-3CF Lesion Generator

ELECTRICAL SUPPLY

Voltage Specifications:

Volts (customer specified)	Volts input range
100Vac	90-110
117Vac	105-125
220Vac	200-240
240Vac	220-260

Maximum input voltage:	260Vac
Maximum voltage on any output connector:	260Vac
Maximum input power:	416VA
Supply current:	3.0 AMP ~ alternating current sinusoidal wave (117V units) 1.6 AMP ~ alternating current sinusoidal wave (220V units)
Fusing:	3.0 AMP (T) Time-lag (117V units) Domestic 1.6 AMP (T) Time-lag (220/240V units) Foreign
Frequency:	50/60 Hz

ENVIRONMENT OPERATING RANGE

Temperature:	50°F-86°F
Humidity:	20%-80% Non-condensing relative humidity
Atmospheric Pressure:	500 hPa - 1060 hPa

IMPEDANCE MONITOR

Range:	0-5000 ohms digital
Resolution:	1 ohm
Accuracy:	10% of full scale

STIMULATOR OUTPUT

Rate:	ONE SHOT, 2, 5, 10, 20, 50, 75, 100, 150, 180, 200 Hz
Duration:	.1, .2, .5, 1.0 ms
Amplitude selectable:	
Voltage stim mode:	0-1 volt 0-10 volts
Constant Current stim mode:	0-1 mA 0-10 mA

RF LESION GENERATOR OUTPUT

Timing:	Selectable:	0-120 seconds
	Accuracy:	.25 second
	Resolution:	±1 second
Volts:	0-100 V	
	Accuracy:	10% of full scale
	Resolution:	±1 volt
Current:	0-999 mA	
	Accuracy:	10% of full scale

	Resolution:	1 mA
Watts:	0-50 watts Max. (40 watts min. into 100Ω load)	
	Accuracy:	10% of full scale
	Resolution:	.1 watt
	Frequency:	500k Hz ± 10%

TEMPERATURE MONITOR

TC1, TC2, and TM drift less than ±2° from ambient temperature

OVER-TEMPERATURE CONTROL

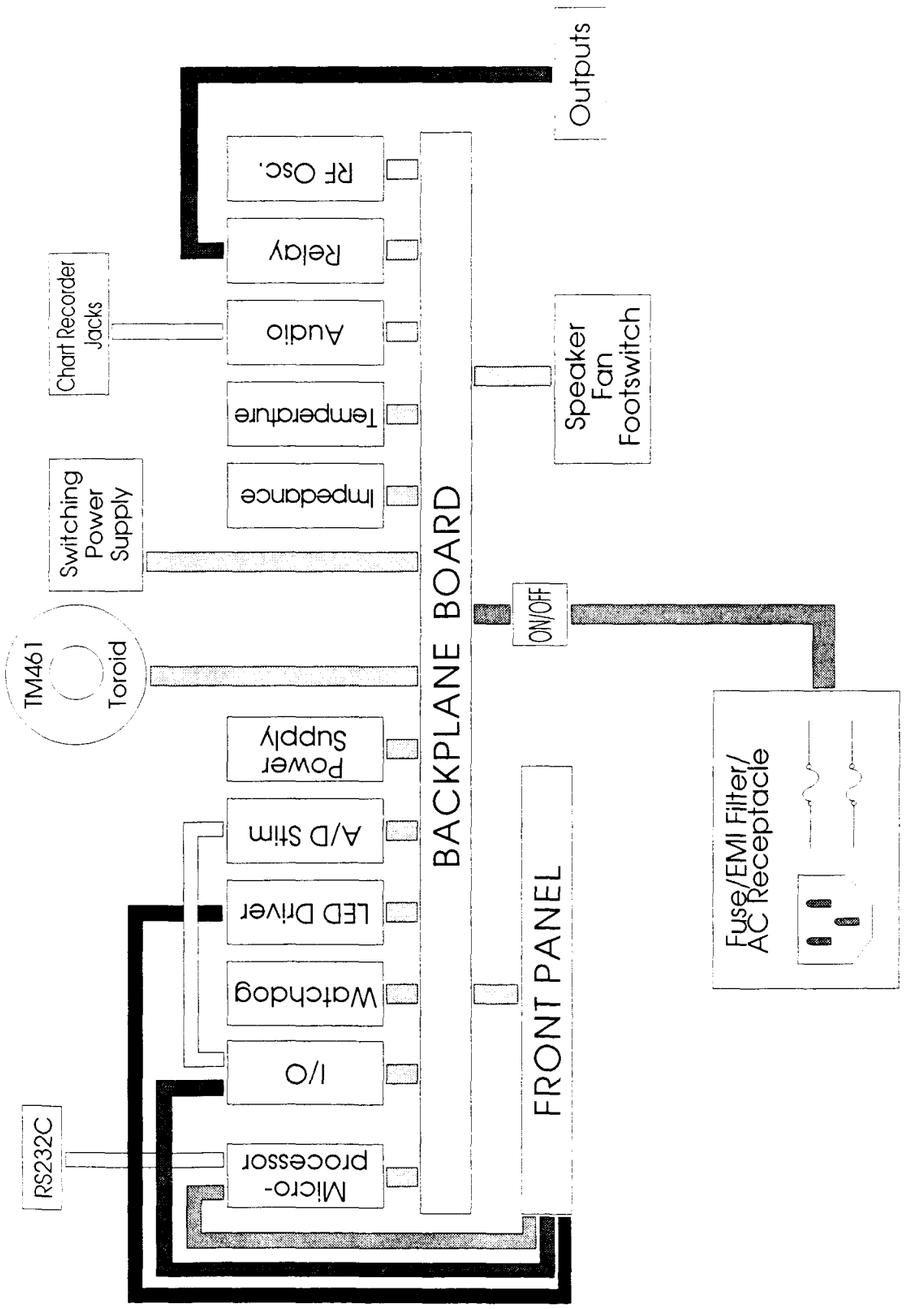
Range:	TC1, TC2, and TM 20-100°C
Resolution:	±1°C

OUTPUT JACKS (BNCs on back panel)

RF Volts	0-100 RF volts	0-1 Vdc +/-20% FS
RF Current	0-1000 RF mA	0-1 Vdc +/-20% FS
RF Watts	0-50 RF watts	0-.5 Vdc +/-20% FS
Impedance	0-5000 ohms	0-1 Vdc +/-20% FS
Temperature	20-100°C	0-1 Vdc +/-20% FS

Notice: The above voltages are nominal since exact calibration is achieved by adjusting the offset and gain controls on the recording device to which this is connected.

Block Diagram of the RFG-3CF



[This page intentionally left blank.]

Appendix E
Accessories

Radionics Part No.	Description
C104-TM	Thermistor Style Electrode Cable
C111-TC	Thermocouple Style Electrode Cable (low power)
C112-TC	Thermocouple Style Electrode Cable
RFG-3C-FS-1	Footswitch (waterproof)
RFG-DGP	Grounding Pad (disposable)
RFG-GP-S	RFG Ground Plate
C118-F	Foreign Power Cord (foreign style, 230 volts)
SRK-14	Thermistor Style Electrode
TEW	Thermocouple Style Electrode
RFG-3C-F(1.6)	1.6 Amp Fuses (220/240V units)
RFG-3D-F(3.0)	3.0 Amp Fuses (100/120V units)